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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/710,801	08/04/2004	Guerry Grune	ACR_001	6748

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EXAMINER	
MARTIN, PAUL C	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/710,801	GRUNE ET AL.	
	Examiner	Art Unit	
	Paul C. Martin	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) *43-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/4/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-59 are pending in this application.

Election/Restrictions

Applicant's election with traverse of Group I (Claims 1-42) in the reply filed on 02/16/07 is acknowledged. The traversal is on the ground(s) that the method and system are closely related, that groups II-V complement group I. This is not found persuasive because the distinctness was clearly set forth in the Office action of 16 Nov 2006.

The requirement is still deemed proper and is therefore made FINAL.

Claims 43-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Although applicants did not comply properly with the election of species, it is withdrawn nevertheless. All of the species are examined on the merits.

Claims 1-42 were examined on their merits.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
The e-signatures are not in correct format, as required under 37 CFR 1.4(d)(2).

The MPEP states:

S-signature . An S-signature is a signature inserted between forward slash marks, but not a handwritten signature as defined by § 1.4(d)(1). An S-signature includes any signature made by electronic or mechanical means, and any other mode of making or applying a signature not covered by either a handwritten signature of § 1.4(d)(1) or an Office Electronic Filing System (EFS) character coded signature of § 1.4(d)(3). Correspondence being filed in the Office in paper, by facsimile transmission as provided in § 1.6(d), or via the Office Electronic Filing System as an EFS Tag(ged) Image File Format (TIFF) attachment, for a patent application, patent, or a reexamination proceeding may be S-signature signed instead of being personally signed (i.e., with a handwritten signature) as provided for in paragraph (d)(1) of this section. The requirements for an S-signature under this paragraph (d)(2) are as follows.<
(i) The S-signature must consist only of letters, or Arabic numerals, or both, with appropriate spaces and commas, periods, apostrophes,.or hyphens for punctuation, and the person signing the correspondence must insert his or her own S-signature with a first single forward slash mark before, and a second single forward slash mark after, the S-signature (e.g., /Dr. James T. Jones, Jr. /);

Drawings

Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, at the time the invention was made, of the specific subject matter claimed.

The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gostelli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41

USPQ2d at 1966." *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In *Regents of the University of California v. Eli Lilly & Co.* the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *Fiers*, 984 F.2d at 1171, 25 USPQ2d 1601; *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 284985 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus ...") *Regents of the University of California v. Eli Lilly & Co.*, 43 USPQ2d 1398.

MPEP § 2163 further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163 does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163.

Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The factors considered in the Written Description requirement are (1) *level of skill and knowledge in the art*, (2) *partial structure*, (3) *physical and/or chemical properties*, (4) *functional characteristics alone or coupled with a known or disclosed correlation between structure and function*, and the (5) *method of making the claimed invention*. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP § 2163.

In the instant case, the claims are drawn to a system comprising a device for the detection of acrylamide in food or food substances comprising a substrate material containing an appropriate enzyme, co-enzyme, and/or some form of energy, and/or a metal, and/or catalyst facilitates conversion of acrylamide to a chemical fragment that can be detected and measured.

(1) Level of skill and knowledge in the art:

Those of ordinary skill in the art would have been familiar with the process of enzymatically converting acrylonitrile (chemical fragment) to acrylamide (Armitage *et al.* (US 5,998,180), what coenzymes are required for the activities of particular enzymes, for example thiamine pyrophosphate (TPP) and coenzyme A for example (CoA) (Frey, (2001).

(2) Partial structure:

The instant disclosure however provides no structural definitions or explanations of what specifically constitutes chemical fragments or reactive chemical fragments of acrylamide, forms of energy, metals and catalysts are encompassed by the instantly claimed invention. No specific definitions of these terms are taught or suggested anywhere in the instant specification.

(3) Physical and/or chemical properties:

The physical properties of chemical fragments or reactive chemical fragments of acrylamide, forms of energy, metals and catalysts of the instant invention are similarly undefined, there being no specific teachings or examples in the specification as to what constitutes the claimed terms.

(4) Functional characteristics:

The terms chemical fragments or reactive chemical fragments of acrylamide, forms of energy, metals and catalysts have also not been suitably described by any functional

characteristics; other than presumably being detectable, energetic, a substance with heat and electrical conductivity, luster and malleability, and able to catalyze something, respectively.

(5) Method of making the claimed invention:

One of ordinary skill in the art would not be able to make the instantly claimed invention as it has not been adequately described so as to allow one to easily ascertain what components are necessary for its construction and practice, what processes the components are involved in acrylamide detection, or what components are required or not for the making and using of the invention.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad genus. Claims 1 and 22 is a broadly generic to all possible chemical fragments or reactive chemical fragments of acrylamide, forms of energy, metals and catalysts encompassed by the claims.

The possible variations are enormous to any class of chemical fragments or reactive chemical fragments, forms of energy, metals and catalysts. Since the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure, it is "not sufficient characteristic for written description

purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. Here, though the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the chemical fragments or reactive chemical fragments, forms of energy, metals and catalysts beyond those disclosed in the examples in the specification, which are only drawn to the enzymatic conversion of acrylamide to either ammonia or acrylonitrile and subsequent detection thereof. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of chemical fragments or reactive chemical fragments (other than ammonia or acrylonitrile), forms of energy, metals and catalysts.

While having written description of the chemical fragments or reactive chemical fragments identified in the specification and/or examples, the specification is devoid of any other chemical fragments or reactive chemical fragments, forms of energy, metals and catalysts that qualify for the functional characteristics claimed.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed

that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 refers to a system comprising a device and necessary materials required for detection of acrylamide. It is unclear what constitutes necessary materials, and the metes and bounds of the claim cannot be readily determined. Claims 2-21 are rejected as being dependent upon Claim 1.

Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "easily detected" in claims 1 and 22 is a relative term which renders the claim indefinite. The term "easily detected" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what is meant by

how easily detection is performed, as opposed to relative difficulty in detecting the acrylamide fragment(s). Simply stating "detected" would be sufficient.

Claims 1-6, 11-26 and 32-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 22 refer to a substrate comprising a material containing an appropriate enzyme. It is unclear what constitutes an appropriate enzyme, or what makes one enzyme more or less appropriate than another. Claims 2-6, 11-21, 23-26 and 32-42 are rejected as being dependent upon Claims 1 and 22.

Claims 3, 5, 6, 12, 13, 14 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 23 refer to a substrate comprising a material containing an appropriate enzyme or other substituent.

It is unclear what constitutes an other substituent, and the metes and bounds of the claim cannot be readily determined. Claims 5, 6, 12, 13 and 14 are rejected as being dependent upon Claim 3.

Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 22 refer to a material containing an appropriate enzyme and/or a co-

enzyme and/or some form of energy and/or a metal and/or catalyst. It is unclear what the device actually comprises, and the metes and bounds of the claim cannot be readily determined.

Further, it is not readily apparent what constitutes some form of energy, which encompasses anything from light waves to electricity. Claims 2-21 and 23-42 are rejected as being dependent upon rejected Claims 1 and 22.

Claims 20 and 40 contain the trademark/trade name Lumi-Cell. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves.

Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a sensor and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 8, 22, 24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Nawaz *et al.* (1994).

Nawaz *et al.* teaches a device for the detection of acrylamide concentration in bacterial media (a bacterial food source) comprising mixing acrylamide with a mineral salts medium amended with micronutrients, placing the solution into a culture containing *Rhodoccus sp.* Bacterium (substrate), comprising an aliphatic amidase, which along with the enhancing metals iron, barium and chromium, facilitates conversion of acrylamide to acrylate and ammonia which are detected and the concentration measured colorimetric ally (ammonia sensitive) and by gas chromatography (acrylate) (Pg. 3343, Column 2, Lines 7-33 and Pg. 3344 Column 2, Lines 12-20 and Fig. 1 and Pg. 3346, Table 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 8, 11, 22, 24, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nawaz *et al.* (1994) in view in view of Skouloubris *et al.* (2001).

The teachings of Nawaz *et al.* were discussed above.

Nawaz *et al.* does not teach wherein the enzyme is AmiE aliphatic amidase.

Skouloubris *et al.* teaches that AmiE aliphatic amidase is homologous to the amidase found in *Rhodococcus sp.* and hydrolyzed acrylamide (Pg. 597, Column 2, Lines 4-16).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method of Nawaz *et al.* for the detection of acrylamide by using an aliphatic amidase with the use of an AmiE aliphatic amidase as taught by Skouloubris *et al.* because both methods are drawn to the use of aliphatic amidases which can hydrolyze acrylamide. The use of alternatives and functional equivalent enzymes would have been desirable to those of ordinary skill in the art based upon the economics and availability of enzymes in question. There would have been a reasonable expectation of success in making this modification because both enzymes are aliphatic amidases which hydrolyze acrylamide and are recognized homologs.

Claims 1, 3, 5, 6, 8, 12-14, 22, 24-26, 28, 32-34 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nawaz *et al.* (1994) in view of Khalil *et al.* (US 2003/0003589 A1).

The teachings of Nawaz *et al.* were discussed above.

Nawaz *et al.* does not teach a system or device wherein the ammonia sensitive detection and measurement technique includes an ammonia sensitive apparatus or strip containing an chromophore recognizing ammonia concentration by correspondence with an electrical signal; a colorimetric display showing the concentration of ammonia detected and a numeric scale representative of the concentration of acrylamide in the food or food substance;

wherein the chromophore is bromophenol blue, bromocresol green or chlorophenol red; or wherein the test is completed at home and is suited for sending to a laboratory for detailed low concentration acrylamide analysis.

Khalil *et al.* teaches a device for ammonia detection and measurement comprising an ammonia sensitive apparatus containing the substrate immobilized chromophores chlorophenol red, bromophenol blue or bromocresol green (Pg. 2, Column 1, Paragraph [0011]), which recognizes ammonia concentration by correspondence with an electrical signal and a numeric scale representative of the concentration of acrylamide (Pg. 4, Column 1, Paragraphs [0026] and [0027]), a colorimetric display showing the concentration of ammonia detected (Pg. 3, Column 1, Paragraph [0019]), wherein the source of ammonia is from enzymatic activity (Pg. 5, Column 1, Paragraph [0038]).

Khalil *et al.* teaches that the substrate immobilized ammonia sensitive dye detects both in liquid and gas states and the insoluble ammonia sensitive dye is prevented from leaching out of

the solid phase in the presence of water or aqueous based liquids, and is insensitive to anions, captions and nonvolatile chemical species (Pgs. 1 and 2, Paragraph [0009]).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the device for the detection of acrylamide concentration in bacterial media by colorimetric ally measuring enzyme generated ammonia with the colorimetric ammonia detection methods because both of the methods of Nawaz *et al.* and Khalil *et al.* are drawn to the detection and measurement of ammonia by colorimetric means. One of ordinary skill in the art would have been motivated to combine these two methods because of the advantages described by Khalil *et al.* of being able to detect ammonia in gas or liquid states and the immobilized ammonia sensitive indicator dye is sequestered from reacting with interfering anions and cations or nonvolatile chemical species are effectively functionally equivalent to the method of Nawaz et al. There would have been a reasonable expectation of success in combining these two methods because both teach the colorimetric detection and quantification of ammonia derived from enzymatic activity.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Martin
Examiner
Art Unit 1657

5/11/07

JON WEBER
SUPERVISORY PATENT EXAMINER